

### **REMARKS**

This responds to the Office Action dated October 15, 2007. Claims 14, 18, 24-29, 31-32 and 39-40 are amended, no claims are canceled, and no claims are added. Claims 14-46 remain pending in this application.

#### **Information Disclosure Statement**

Applicant submits with this response an Information Disclosure Statement and a 1449 Form. Applicant respectfully requests that an initialed copy of the 1449 form be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

#### **§112 Rejection of the Claims**

Claims 14-46 were rejected under 35 U.S.C. § 112, first paragraph. The rejection asserts that the claims failed to comply with the written description requirement. Specifically, the rejection asserts that the original specification used the range of “one or more” or “at least one” available detection enhancement, and that “two or more available detection enhancements” or “at least two . . . enhancements” was not described in the specification.

Applicant respectfully traverses. The original specification refers to “detection enhancements.” The plural form of “enhancement” clearly indicates to one skilled in the art that the “detection enhancements” refer to more than one enhancement, and that “two or more” or “at least two” enhancements also refer to more than one enhancement.

Regarding the available detection enhancements that are available for selection, Applicant has chosen to remove “two or more” and “at least two” to remove this issue from prosecution. Applicant requests withdrawal of the rejection.

Claim 18 was rejected under 35 U.S.C. § 112, second paragraph. Applicant requests consideration of amended claim 18, and withdrawal of the rejection.

*The §102 and §103 Rejections*

The rejection has not applied the language of the claims against the reference. For example, the rejection has not clearly identified what is considered to be a detection enhancement and what is considered to be a parameter in Snell. Applicant requests the Office to clearly identify the portion of Snell (and the specific elements therein) relied upon in the rejection, and then clearly apply the language of the claims against specific portions of the reference. If the Office cannot make such a showing, Applicant respectfully submits that it is impossible for the Office to show that the reference anticipates the claims.

The Office generally refers to FIG. 5 as showing the selection of atrial fibrillation, and FIG. 6 as plurality of detection enhancements as the different ways that therapy is required. FIGS. 5-6 are identified as a decision tree that can be used as a rule set for reaching a therapy recommendation (col. 4 lines 55-59). The decision tree presents questions that the physician answers, uses the answers to present more questions, etc. to present a programming recommendation to the physician.

Item 5 in FIG. 5 asks the question “Is there evidence of atrial fibrillation?” This is part of the decision tree to recommend a therapy, and does not illustrate a selected clinical rhythm that makes detection enhancements available for selection by the user. It appears that the physician can answer none or chronic or intermittent. (Col. 24 lines 65-66). If the physician answers that there is evidence of intermittent AF, item 7 in FIG. 6 asks when the pacemaker is required (for the intermittent AF), and it appears that the physician can answer 1. during atrial fib., 2. immediately after conversion. 3. during sinus rate due to marked bradycardia. The physician’s answers are not rules for determining when to deliver shock therapy for the selected clinical rhythm.

The question of item 7 and answers are guidance for physicians and medical technicians in programming parameters (Abstract; col. 3 lines 42-44 (the rule engine engages an operator in an interactive question and answer session (according to rules of a selected rule set) and displays an operating condition as a programming recommendation based on the information from the operator). The rules sets are based on the type of implantable cardiac stimulating device to be programmed. (col. 3 lines 35-40). These rules relate to the specific decision tree for a specific device, not determining when to deliver shock therapy for a selected clinical rhythm.

The rejection states: *Snell . . . discusses the plurality of detection enhancements (set of rules for when to deliver therapy) as the different ways that therapy is required (e.g. figure 6, such as when intermittent AF),*” This is unclear, and does not comply with 37 CFR §1.104 (“The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant . . . to judge the propriety of continuing the prosecution.” 37 CFR §1.104(a)(2).) An answer provided by the physician is not a rule. An answer provided by the physician is not a detection enhancement.

The response to Applicant’s arguments is also confusing.

On page 9, the rejection stated: *The argument that the claims use the terms “clinical rhythm, detection enhancement, and parameter” is correct, although no specific definition has been set forth in the specification for these terms and therefore they have been given their broadest reasonable interpretation as described above in the rejections.* This too is unclear, and does not comply with 37 CFR §1.104 Applicant appreciates that the Office give the terms their broadest reasonable interpretation. However, if the Office is unable to clearly identify what in the reference is a clinical rhythm, what in the reference is a detection enhancement, and what in the reference is a parameter, the Office’s “interpretation” is not reasonable. When the claims and specification both distinctively use the terms “parameters” and “detection enhancements,” Applicant asserts it is unreasonable to interpret a detection enhancement as merely an example of a parameter. Otherwise, for this example, the claims would recite that the parameter (detection enhancement) includes one or more parameters. This is not a distinctive use of the terms “detection enhancement” and “parameter”.

On page 9, the rejection further stated: *The argument that Snell fails to show a selected clinical rhythm and at least one parameter forming at least a portion of a detection enhancement is incorrect since Snell programs the implantable device with “at least one parameter” since he programs at least the mode of the IMD.* Applicant traverses. The Office has not shown a detection enhancement for the clinical rhythm, and the parameters for the detection enhancement. A question presented to the physician asking the physician when the pacemaker is required is not a detection enhancement for atrial fibrillation, nor is a list of answers that can be selected by the physician.

On page 9, the rejection further stated: *The argument that the office action improperly equates parameter and detection enhancements is not persuasive. The 103 rejection on page 4, line 7 of the previous office action was not equating the “claimed” parameter to a detection enhancement, but the general definition of a parameter (e.g. a factor that defines a system, a limiting factor, a notable characteristic, etc.), “such as a detection enhancement”, and how artificial intelligence can be used to select a parameter/detection enhancement.* This is unclear. Should the rejection be maintained, Applicant requests clarification. Applicant appreciates that the Office give the terms their broadest reasonable interpretation. However when the claims and specification both distinctively use the terms “parameters” and “detection enhancements,” Applicant asserts it is unreasonable to interpret a detection enhancement as merely an example of a parameter. When the Office applies the reference to the language of the claims, the Office needs to clearly identify the element(s) in the reference relied upon as the detection enhancement and the element(s) in the reference relied upon as the parameter, and consistently apply those elements throughout the entire claim. The elements should be consistently used throughout the reference.

#### §102 Rejection of the Claims

Claims 14-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Snell (U.S. Patent No. 5,716,382). Applicant respectfully traverses the rejection.

The specification and the claims (e.g. claims 14-15) distinctly use the terms “clinical rhythm, detection enhancement, and parameter. As addressed in Applicant’s specification, for example, appropriate enhancements can be programmed by a process of selection (e.g. *Specification* at page 5, line 14, lines 7-19). A user-provided selection of a clinical rhythm is received (e.g. *Specification* at page 6, lines 13-17), the clinical rhythm is associated with one or more available detection enhancements that are made available based on the selected clinical rhythm, where the available detection enhancements are available for selection by the user to add specificity for determining when to deliver shock therapy for the selected clinical rhythm (e.g. *Specification* at page 6, lines 18-21). Each detection enhancement can include at least one modifiable parameter (e.g. *Specification* at page 6, lines 21-24).

With respect to independent claim 14, Applicant is unable to find in Snell, among other things, a showing or suggestion of a programmer comprising a first and second module as recited in the claim. The recited first module receives a user-provided selection of a clinical rhythm. The clinical rhythm is associated with available detection enhancements that are made available based on the selected clinical rhythm for selection by the user to add specificity for determining when to deliver shock therapy for the selected clinical rhythm. The available detection enhancements are sets of rules for determining when to deliver shock therapy for the selected clinical rhythm. The recited first module is preprogrammed to provide a selection of at least one detection enhancement from the available detection enhancements that are associated with the clinical rhythm. The recited second module receives a user-provided selection to modify the selection of the at least one detection enhancement provided by the preprogrammed first module to at least one other detection enhancement from the two or more available detection enhancements that are associated with the clinical rhythm.

Claims 15 and 16 depend on independent claim 14. These dependent claims recite additional features, and are believed to be allowable at least for the reasons provided with respect to claim 14. Further, with respect to claim 15, Applicant is unable to find a first module preprogrammed to provide a setting for at least one parameter for the at least one detection enhancement, and a second module that receives a user-provided selection to modify the setting for the at least one parameter. Additionally, with respect to claim 16, Applicant is unable to find a communication module for communicating with a pulse generator to program the pulse generator with the at least one detection enhancement.

Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested.

§103 Rejection of the Claims

Claims 17-21, 30-34, 37 and 39

Claims 17-21, 30-34, 37 and 39 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Snell (U.S. Patent No. 5,716,382). Applicant respectfully traverses the rejection.

Claim 17 depends on independent claim 14 and is believed to be in a condition for allowance at least for the reasons provided with respect to independent claim 14. Further, Applicant is unable to find a number of layered screen displays where a first screen provides a capability to activate at least one detection enhancement seeded with at least one parameter, and a second screen provides a capability to change the at least one parameter for the at least one detection enhancement. Applicant respectfully requests withdrawal and reconsideration and allowance of claim 17.

With respect to independent claim 18, Applicant is unable to find in Snell, among other things, the recited selection module and the recited parameter modification module. Applicant cannot find a selection module that receives a selection of a clinical rhythm from a user where the clinical rhythm is associated with available detection enhancements wherein the available detection enhancements are sets of rules to determine when to deliver shock therapy and that include at least one parameter. Applicant cannot find a selection module that includes artificial intelligence adapted to select a detection enhancement from the available detection enhancements and provide a setting for the at least one parameter for the selected detection enhancement. Applicant cannot find a selection module that receives a user provided selection of at least one other detection enhancement from available detection enhancements in place of the detection enhancement selected by artificial intelligence. Applicant cannot find a parameter modification module that receives a user input to change the setting for the at least one parameter of the selected detected enhancement. Claims 19-21 and 30 depend, either directly or indirectly, on independent claim 18. These dependent claims recite additional features, and are believed to be allowable at least for the reasons provided with respect to claim 18. Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested with respect to claims 18-21 and 30.

With respect to independent claim 31, Applicant is unable to find in Snell, among other things, a programmer that comprises the recited control logic and the recited display. Applicant cannot find in Snell control logic that programs the pulse generator to detect and provide therapy for at least one clinical rhythm, programs the pulse generator with at least one selected detection enhancement from the available detection enhancements associated with the at least one clinical rhythm, and programs the pulse generator with at least one parameter for the at least one selected

detection enhancement. Applicant cannot find in Snell a display that provides a number of screen displays used by the user to select the at least one clinical rhythm and modify the selection of the at least one detection enhancement from at least one preprogrammed detection enhancement to at least one other detection enhancement from the available detection enhancements associated with the at least one clinical rhythm.

Claims 32-34, 37 and 39 depend, either directly or indirectly, on independent claim 31. These dependent claims recite additional features, and are believed to be allowable at least for the reasons provided with respect to claim 31. Additionally, with respect to claim 32, Applicant is unable to find, among other things, in the cited portions of Snell, a programmer where the at least one selected detection enhancement is automatically seeded with a value for the at least one parameter, and the number of screen displays are used by the user to change the value for the at least one parameter. Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested.

Claims 22-23 and 38

Claims 22-23 and 38 were rejected 35 U.S.C. § 103(a) as being unpatentable over Snell (U.S. Patent No. 5,716,382) as applied to the claims above.

Claims 22 and 23 are dependent upon independent claim 18. Claim 38 is dependent upon independent claim 31. These dependent claims recite additional features, and are believed to be allowable at least for the reasons provided with respect to independent claims 18 and 31. Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested.

*Double Patenting Rejection*

Claims 14-23 and 30-40 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending Application No. 11/369,142 and over claims 1-27 of Application No. 11/379,742. Claims 14-23, 30-34 and 37-39 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,493,579. Claims 14-23, 30-34 and 37-39 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 16 of U.S. Patent No. 6,522,925.

Applications 11/379742 and 11/379742 have not issued at the time of this response.

Should the Office choose to maintain the rejection, Applicant respectfully requests the Office to clarify how the present application provides an unjustified extension of later-filed 6,522,925 patent. Obviousness-type double patenting requires rejection of an application claim when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. (See MPEP 804). U.S. Patent 6,522,925 was filed on May 13, 2000. The present application claims priority to August 20, 1999.

Applicant will appropriately address the rejections, including any provisional rejections, when the claims of this application are otherwise found to be in condition for allowance.



**CONCLUSION**

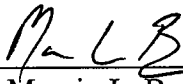
Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6960 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

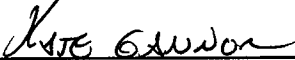
Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6960

Date 10-30-07

By   
Marvin L. Beekman  
Reg. No. 38,377

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 30 day of October 2007.



Name



Signature